Rubius Therapeutics Highlights Preclinical Oncology Data at Society for Immunotherapy of Cancer Annual Meeting and AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics

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CAMBRIDGE, Mass., Nov. 08, 2019 (GLOBE NEWSWIRE) -- Rubius Therapeutics, Inc. (Nasdaq: RUBY), a clinical-stage biopharmaceutical company that is genetically engineering red blood cells to create an entirely new class of cellular medicines, today announced that the Company presented preclinical data supporting its lead artificial antigen presenting cell program, RTX-321, for the potential treatment of HPV 16-positive tumors at the Society for Immunotherapy of Cancer (SITC) 34th Annual Meeting. Last month at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer, Rubius Therapeutics presented data demonstrating that its Red Cell Therapeutics™ can be engineered to create a loadable system for personal neoantigens, unlocking a potential new use of our RED PLATFORM®.

“Current cell therapy approaches are limited by a number of challenges – they require harvesting and engineering a patient’s own T cells, undergo a lengthy manufacturing process, are limited in the number of targets that can be pursued, and, once administered to patients, can elicit unpredictable immune responses, including severe side effects. Today at SITC, we presented additional preclinical proof of concept data demonstrating that Rubius Therapeutics can engineer allogeneic artificial antigen presenting cells against a tumor-associated antigen that significantly expand antigen-specific T cells and nearly eliminates lung metastases in a melanoma mouse model with minimal, reversible toxicity,” said Pablo J. Cagnoni, M.D., chief executive officer of Rubius Therapeutics. “Separately, current personalized neoantigen approaches are promising, but do not adequately stimulate and expand the right subset of T cells to the levels required to achieve robust efficacy. Last month at AACR-NCI-EORTC, Rubius Therapeutics presented data showing that we can engineer our red cells to create a loadable system for personal neoantigens and dramatically expand primary T cells to induce an immune response, unlocking a potential new use of our RED PLATFORM®.”

Data Summaries

Red Cell Therapeutic™ Artificial Antigen Presenting Cells (aAPCs) at SITC

(P233) RTX-321, an Allogeneic Artificial Antigen Presenting Red Cell Therapeutic, Expressing MHC I-Peptide, 4-1BBL and IL-12, Promotes Antigen-Specific T Cell Expansion and Anti-Tumor Activity in HPV16+ Tumors

- Allogeneic Red Cell Therapeutic artificial antigen presenting cells (RTX-aAPCs) are engineered to induce a tumor-specific response by expanding antigen-specific T cells.
- As preclinical proof of concept, mouse red cells were chemically engineered with hundreds of thousands of copies of the major histocompatibility complex (MHC) I loaded with the gp100 peptide, a melanoma antigen, 4-1BBL and IL-12 on the cell surface and were tested in a B16-F10 melanoma mouse model.
    - These cells (mRBC-gp100-4-1BBL-IL-12) nearly eliminated lung metastases at the highest dose levels.
    - mRBC-gp100-4-1BBL-IL-12 promoted gp100-specific T cell expansion in the circulation, secondary lymphoid organs and lungs.
- RTX-aAPC was engineered with a cytomegalovirus (CMV) antigen, 4-1BBL and IL-12 and expanded CMV-specific T cells from healthy donor peripheral blood mononuclear cells (PBMCs).
- RTX-321 (HPV+) was engineered to express an HPV peptide antigen bound to MHC I, 4-1BBL and IL-12 on the cell surface to mimic human T cell-APC interactions.
    - Expression of IL-12 as signal 3 on an aAPC resulted in more robust antigen-specific T cell expansion, memory formation and cytotoxicity against tumor cells when compared to IL-7 or IL-15, leading the Company to select IL-12 as signal 3 for RTX-321.
    - RTX-321 is selectively directed against an HPV dominant epitope and promoted T cell receptor (TCRs), 4-1BB and IL-12 receptor signaling in engineered cell lines.
    - RTX-321 expanded HPV-specific TCR-transduced primary human T cells.
    - RTX-321 is currently in IND-enabling studies.

Loadable Red Cell Therapeutic Artificial Antigen Presenting Cells for Neoantigens at AACR-NCI-EORTC

(B062) Enabling the Rapid Generation of Allogeneic Artificial Antigen Presenting Cell (aAPC) Red Cell Therapeutics with a Loadable MHC System

- Allogeneic Red Cell Therapeutic artificial antigen presenting cells (RTX-aAPCs) are engineered to induce an tumor-specific response by expanding antigen-specific T cells.
- A loadable MHC system was engineered to enable the rapid generation of aAPCs targeting personal neoantigens.

- Antigenic peptides can be loaded onto empty MHC constructs, which can be stably expressed at high levels.
- RTX-aAPCs with peptide-loaded MHC constructs functionally engaged TCRs and achieved robust expansion of primary CMV-specific T cells in healthy donor PBMCs with prior exposure to CMV.
- Rubius Therapeutics' loadable aAPC system has the potential to generate aAPCs containing multiple neoantigens in a single therapeutic.
- Further development of a loadable aAPC system may enable effective personalized neoantigen therapies.

About Rubius Therapeutics

Rubius Therapeutics is a clinical-stage biopharmaceutical company developing a new class of medicines called Red Cell Therapeutics™. The Company's proprietary RED PLATFORM ® was designed to genetically engineer and culture Red Cell Therapeutics™ that are selective, potent and off-the-shelf allogeneic cellular therapies for the potential treatment of several diseases across multiple therapeutic areas. Rubius' initial focus is to advance RCT™ product candidates for the treatment of rare diseases, cancer and autoimmune diseases by leveraging three distinct therapeutic modalities — cellular shielding, potent cell-cell interaction and tolerance induction. For more information, visit www.rubiustx.com, or follow us on Twitter and LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding our expectations regarding the therapeutic potential of our RED PLATFORM, Red Cell Therapeutic artificial antigen presenting cells and RTX-321, our expectations regarding IND-enabling studies for RTX-321, our expectations regarding the potential therapeutic benefits of RTX-321, our expectations regarding the potential expansion of uses of our RED PLATFORM and our strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "goal," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those risks and uncertainties related to the development of our RCT product candidates and their therapeutic potential and other risks identified in our SEC filings including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, and subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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